K102816

SEP 15 2011

510(k) Summary

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Date Prepared:	September 13, 2011
Trade Names:	GAL-1C Blood Glucose Monitoring System GAL-1C Blood Glucose Test Strips Contrex Plus III Glucose Control Solution
Classification:	Glucose test system, 21 CFR 862.1345, Class II Single (specified) analyte controls (assayed and unassayed), 21 CFR 862.1660, Class I
Product Codes:	CGA, NBW, JJX
Predicate Device:	GlucoSure STAR Blood Glucose Monitoring System (k073648) Contrex Plus Glucose Control Solution (100747)
Device Description:	The GAL-1C blood glucose meter and GAL-1C test strips used for testing of blood glucose by self-testers at home with Contrex Plus III Glucose Control Solutions for quality control testing.

510(k) Summary (Continued)

Intended Use:	The GAL-1C Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. The GAL-1C Blood Glucose Test Strips are to be used with the GAL-1C Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use. The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.
Comparison of Technological Characteristics:	The GAL-1C meter uses the same test algorithm as the predicate meter. The GAL-1C meter has been modified by changing 4 operating buttons to 3 operating buttons. Meter software has been changed to accommodate the new autocoding feature. The test strip holder has been modified to allow automatic detection of the calibration code upon insertion of the test strip. The test strip chemistry has been slightly modified and the blood collection chamber has been reduced in volume. The Contrex Plus III Control Solution includes an added red dye and slightly modified glucose concentrations.
Non-Clinical Testing:	Testing was conducted as follows: Software verification and validation, software integration, linearity, Lo/Hi detection, drop testing, EMC and Electrical Safety, verification of strip noninterchangeability between new and predicate devices, precision, interferences, minimum sample volume, altitude, hematocrit, humidity and temperature, control solution qualification, environmental conditions testing, test strip shelf life and use life, control solution shelf life and use life, and battery life testing. Disinfection testing was done to show that the system remained accurate after multiple disinfections to simulate a life time of disinfection treatments. Evaluation was done to demonstrate the ability of the selected disinfectant material to inactive Hepatitis B. Results demonstrate substantial equivalence to the predicate device meter, test strips, and control solutions.
Clinical Testing	An accuracy study was performed with blood testing by healthcare professionals. A User Performance study was conducted with self-testing at finger, palm, and forearm sites. A User Study was conducted to evaluate ease-of-use of the system and ease-of-understanding of the User's Manual. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the GAL-1C system performs in a substantially equivalent manner to that of the predicate system. We conclude that the GAL-1C meter and GAL-1C test strips are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Re: k102816
Trade/Device Name: GAL-1C Blood Glucose Monitoring System, GAL-1C Blood Glucose Test Strips, and Contrex Plus III Glucose Control Solutions
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: August 22, 2011
Received: August 23, 2011

Dear Sir/Madam

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k102816

Device Name: GAL-1C Blood Glucose Monitoring System

Indications for Use:

GAL-1C Blood Glucose Monitoring System:

The GAL-1C Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

GAL-1C Blood Glucose Test Strips:

The GAL-1C Blood Glucose Test Strips are to be used with the GAL-1C Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k102816

Indications for Use Statement

510(k) Number (if known): k102816

Device Name: Contrex Plus III Glucose Control Solutions

Indications for Use:

Intended use
The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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